

REMARKS/ARGUMENTS

Claims 57-69 are currently pending in this application. Claims 57-68 are rejected in the Office Action of April 23, 2003. Claim 57 is hereby amended. Claim 64 is hereby canceled without prejudice or disclaimer. Support for the amendment to claim 57 can be found in the specification on page 19, lines 25-28. New claim 69 is hereby added. Support for new claim 69 can be found in the specification on page 19, lines 22-23, and in original claim 57.

Rejections under 35 U.S.C. § 102(b)

Claim 57 is rejected under 35 U.S.C. § 102(b) as anticipated by Erickson (US Pat. No. 3,751,569, hereinafter referred to as "Erickson"). Claim 57 is hereby amended to recite "an edible oil comprising more than 10% of a sterol fatty acid ester composition, wherein the sterol fatty acid ester composition comprises more than 50% monounsaturated fatty acid (MUFA) moieties; wherein the edible oil that contains the sterol fatty acid ester composition remains clear upon addition of the sterol fatty acid ester composition; and wherein the edible oil that contains the sterol fatty acid ester composition is free of solids at temperatures of greater than about 60°F."

Erickson does not disclose an edible oil containing more than 10% of a sterol fatty acid ester composition. In addition, Erickson teaches an oil containing a plant sterol monocarboxylic acid ester in a range from 0.5% to 10% (free sterol equivalent) by weight of the total cooking and salad oil composition. (Erickson, column 2, lines 25-29). Erickson goes on to explain that 10% was chosen as a "practical upper limit" because most plant sterol esters were found not sufficiently soluble at levels above 10% (free sterol equivalent) by weight. (Erickson, column 2, lines 35-39). Furthermore, Erickson shows the solubilities (free sterol equivalent) of several plant sterol fatty acid esters in Table II in column 5. None of the solubilities are greater than 10%. In fact, the most soluble, the oleate sterol ester, was only reported to be soluble at a level of 7.9% (free sterol equivalent). Accordingly, since Erickson does not disclose an edible oil containing more than 10% of a sterol fatty acid ester composition as claimed in amended claim 57, amended claim 57 is not anticipated by Erickson.

Rejections under 35 U.S.C. § 103(a)

Claims 57-68 are rejected under 35 U.S.C. § 103(a) over Miettinen, *et al.* (US Pat. No. 5,502,045, hereinafter referred to as "Miettinen") and Wester, *et al.* (WO 99/56558, hereinafter referred to as "Wester.") Because Miettinen and Wester do not teach or suggest an edible oil comprising more than 10% of a sterol fatty acid ester composition, wherein the sterol fatty acid ester composition comprises more than 50% monounsaturated fatty acid (MUFA) moieties; wherein the edible oil that contains the sterol fatty acid ester composition remains clear upon addition of the sterol fatty acid ester composition; and wherein the edible oil that contains the sterol fatty acid ester composition is free of solids at temperatures of greater than about 60°F, Applicant respectfully disagrees. While Miettinen and Wester do both teach the therapeutic effectiveness of sterol esters for reducing serum cholesterol levels that is not what Applicant claims in this application. Furthermore, that teaching does not provide the requisite motivation to modify either of these references to produce Applicant's claimed invention. Furthermore, Miettinen nor Wester, nor a combination thereof teach or suggest Applicant's claimed

invention—an edible oil that is clear at room temperature and contains more than 10% of a sterol fatty acid ester composition wherein more than 50% of the fatty acid moieties are monounsaturated fatty acid moieties. Neither Miettinen or Wester teach or suggest that such a clear edible oil can be made, and Wester actually teaches that the only way to satisfactorily add levels of more than 10% of a sterol fatty acid ester to a clear edible oil is to use more than 50% **polyunsaturated** fatty acids when making the sterol fatty acid esters.

Examiner states that one of ordinary skill in the art would have been motivated to employ more than 50%, about 55-80%, or about 60-70% of monounsaturated fatty acid moieties and less than 50% polyunsaturated fatty moieties based on the teachings of Wester and Miettinen. This is directly contrary to the teachings of Wester. First, Wester, on page 3, first full paragraph, specifically cites Miettinen in its review of the prior art. Wester cites Miettinen as showing a way of adding plant sitostanol esters to oil, which can then be blending into foods like margarines and spreads, (page 3, lines 20-21) *i.e.* foods where the clarity of the oil blend is not a consideration. Second, on the next page, at the end of the review of the prior art, Wester states that the problem with the cited prior art is that, in spite of the esterification of the phytosterols, the prior art still does not provide the desired amounts of phytosterols for “optimum effect on blood sterol levels. (Wester, page 4, first full paragraph). That is to say, Wester characterizes the Miettinen patent as not providing sufficient phytosterol esters for the desired hypocholesterolemic effect. Wester goes on to say that that by using the sterol and/or stanol esters of his invention—**high, i.e. greater than 50% PUFA sterols and/or stanols**—one can achieve the optimum levels because the high PUFA sterols and stanols can be added to vegetable oil based food products, like salad oils, cooking oils, and salad dressings, for example, without adversely affecting the clarity like the prior art sterol and/or stanol esters. (Wester, page 4, lines 10-14). Again, Wester teaches us that the prior art stanol esters, including those of Miettinen, as explicitly discussed in the Wester application, are not suitable for use in clear oil products, such as salad oils, cooking oils, salad dressings, and so forth.

Accordingly, the motivation to combine Miettinen and Wester required under MPEP 2143.01 does not exist. First, there is no suggestion or motivation to combine the references. Wester specifically teaches that it is an improvement over Miettinen—the product of Miettinen was unsatisfactory. The stanol esters of Miettinen could not be used to provide optimal results. The stanol esters of Miettinen could not be used in the desired concentrations in clear oils. Wester teaches that by using more than 50% PUFAs to form the esters, and specifically by enriching the PUFA concentration over the naturally occurring amount, optimal results are achieved. By using the high PUFA concentration for esterification, the resulting sterol esters can now be added to clear oils. Wester nowhere suggests that MUFAs could be used in the esterification rather than PUFAs. To the contrary, Wester teaches that only by using a high level of PUFAs can the desired results, *i.e.*, optimum levels of sterol esters and the ability to use sterol esters in clear oils, be achieved. Reading the disclosures of Wester and Miettinen would not lead one of ordinary skill in the art to Applicant’s claimed invention. Combination of Wester and Miettinen would not lead one of ordinary skill in the art to believe there is a reasonable chance of success.

Finally, even if one were to read Miettinen alone, there is no suggestion within Miettinen that plant sterol fatty acid esters can be added to clear edible oils at levels of 10% or greater.

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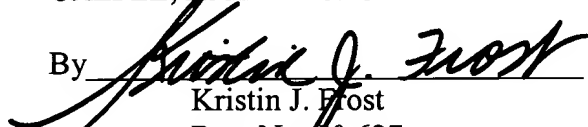
Rather, Miettinen teaches adding sterol fatty acid esters to clear edible oils at levels of up to 6%. (Miettinen, Example 3). Whenever higher levels of plant sterol fatty acid esters are taught in Miettinen, they are added to an opaque product, such as mayonnaise (up to 13%, Example 2) or margarine (up to 20%, Example 5). Nowhere does Miettinen teach or suggest that plant sterol esters, particularly those made with greater than 50% MUFAs may be added to clear edible oils at levels of 10% or greater while maintaining the clarity of the oil at room temperature. Further, upon reading the teachings of Wester, which cites Miettinen as prior art, as discussed above, one of ordinary skill in the art would not be motivated to make an edible oil comprising more than 10% of a sterol fatty acid ester composition, wherein the sterol fatty acid ester composition comprises more than 50% monounsaturated fatty acid (MUFA) moieties; wherein the edible oil that contains the sterol fatty acid ester composition remains clear upon addition of the sterol fatty acid ester composition; and wherein the edible oil that contains the sterol fatty acid ester composition is free of solids at temperatures of greater than about 60°F, as claimed by Applicants.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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By


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